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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,374	07/11/2001	Steve A. Herweck	ATA-297	8317

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EXAMINER	
MATHEW, FENN C	

ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 08/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/903,374	Applicant(s) HERWECK ET AL.	
	Examiner Fenn Mathew	Art Unit 3764	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/11/2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-5 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martakos et al. (U.S. Patent No. 5,897,587). Martakos discloses a prosthesis comprising a first tube (20) of biologically compatible material having an exterior surface, a membrane of polymer material (30), and a support structure wound along a winding axis about the first outer tube (24) to form axially spaced-apart ridges, the membrane having a microstructure of nodes interconnected by fibrils effective to facilitate bonding of the support structure to the membrane. Martakos does not disclose having the membrane connected to the exterior of the tube, and then having the support structure helically wound around the membrane. Martakos discloses the support structure wound around the first tube, with the membrane secured on top of the support structure. Applicant has not stated the criticality of positioning of the members, therefore it would have been obvious to one having ordinary skill in the art at the time of invention to place the membrane over the exterior of the first tube, and have the support structure wound helically around the membrane, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70.

3. Referring to claim 2, Martakos et al. disclose a prosthesis wherein the support structure includes metal wire. (Column 6, lines 34-35).

4. Referring to claim 3, Martakos et al. teach providing a membrane layer over the support structure. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the modified Martakos prosthesis with an outer covering in order to protect the support structure.

5. Referring to claim 4, Martakos et al. disclose ridges spaced apart at a distance effective to direct a needle to a puncture site at an angle that inhibits needle plowing and hole enlarging (column 6, lines 8-16). The feature of having the spaced apart distance being less than or equal to 1.5 times the outer diameter of the needle is a matter of obvious design choice within the realm of one with ordinary skill in the art.

6. Referring to claim 5, Martakos et al. disclose the first tube, support structure, and membrane coalesced by heat (see Martakos claim 5).

7. Referring to claim 8, Martakos et al. disclose a membrane formed from a polymer material having a microstructure of nodes interconnected by fibrils with a porosity that is less than that of the first tube. Inherently, the node size of the membrane would be smaller than that of the first tube. (Column 3, lines 4-10).

8. Referring to claim 9, Martakos discloses a prosthesis wherein the nodes of the membrane are at least 10% less than that of the first tube. (Column 3, lines 4-10).

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martakos et al. (U.S. Patent No. 5,897,587). Martakos et al. disclose a prosthesis comprising an inner tube of polymer material having an inner tube of polymer material

having an exterior surface, a membrane of polymer material, and a support structure wound along a winding axis about the inner tube to form axially spaced-apart ridges, the membrane having a microstructure of nodes interconnected by fibrils, the nodes being oriented at an angle relative to the winding axis effective to facilitate bonding of the support structure. Martakos discloses the support structure wound around the first tube, with the membrane secured on top of the support structure. It would have been obvious to one having ordinary skill in the art at the time of invention to place the membrane over the exterior of the first tube, and have the support structure wound helically around the membrane, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70. Furthermore it would have been obvious to one having ordinary skill in the art at the time of invention to have the support structure on the outside of the membrane in order to enable the material to substantially close a hole created in the membrane when the material is punctured by a needle.

10. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martakos et al. (U.S. Patent No. 5,897,587) as applied to claim 1 above, and further in view of Campbell et al. (U.S. Patent No. 5,747,128). Martakos et al. disclose the claimed invention except for the specific orientation of the nodes forming the membrane microstructure. Campbell et al. teach a membrane microstructure wherein the nodes are oriented at an angle relative to a winding axis of a support structure (13), with the angle being less than 0° relative to the winding axis. (See Campbell figure 1). It would have been obvious to one having ordinary skill in the art at the time of invention to

provide Martakos's implant with the microstructure taught by Campbell in order to inhibit excessive tearing of the membrane when punctured by a needle or cannula.

11. Referring to claim 7, Martakos discloses the claimed invention except for the specific orientation of the nodes with respect to the winding axis of the support structure. Campbell et al. teach a membrane microstructure wherein the nodes are oriented in a direction substantially perpendicular to the winding axis. (See Campbell figure 1). It would have been obvious to one having ordinary skill in the art at the time of invention to provide Martakos's implant with the microstructure taught by Campbell in order to inhibit excessive tearing of the membrane when punctured by a needle or cannula.

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martakos et al. (U.S. Patent No. 5,897,587) in view of Inoue (U.S. Patent No. 5,976,179). Martakos et al. disclose a prosthesis comprising an inner tube of polymer material having an inner tube of polymer material having an exterior surface, a membrane of polymer material, and a support structure wound along a winding axis about the inner tube to form axially spaced-apart ridges, the membrane having a microstructure of nodes interconnected by fibrils, the nodes being oriented at an angle relative to the winding axis effective to facilitate bonding of the support structure. Martakos discloses the support structure wound around the first tube, with the membrane secured on top of the support structure. It would have been obvious to one having ordinary skill in the art at the time of invention to place the membrane over the exterior of the first tube, and have the support structure wound helically around the

membrane, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70. Furthermore it would have been obvious to one having ordinary skill in the art at the time of invention to have the support structure on the outside of the membrane in order to enable the material to substantially close a hole created in the membrane when the material is punctured by a needle. Martakos does not teach use of rings as a support structure, but does disclose that use of rings (column 2, lines 46-50) in a support structure is well known in the art. Inoue (U.S. Patent No. 5,976,179) teaches use of rings (12) in a support structure. It would have been obvious to one having ordinary skill in the art at the time of invention to substitute a support structure comprising of at least two rings as taught by Inoue for the helically wound support structure disclosed by Martakos et al. in order to provide a support structure that inhabits a smaller area of the prosthesis.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martakos et al. (U.S. Patent No. 5,897,587). Martakos et al. disclose a method for making a prosthesis comprising the steps of providing a first tube of biologically compatible material, winding at a support structure along a winding axis to form axially spaced apart ridges on the exterior surface, and positioning a membrane of polymer material about the exterior surface of the tube with entwined support structure. The material is capable of closing a hole created when the material is punctured by a needle or cannula, and the ridges are spaced apart at a distance effective to direct a needle to a puncture site at an angle that inhibits needle plowing and hole enlarging, the membrane having a microstructure of nodes connected by fibrils effective to facilitate

bonding of the support structure to the membrane and inhibit delamination. Martakos et al. differs in the positioning of the support structure. It would have been obvious to one having ordinary skill in the art at the time of invention to place the membrane over the exterior of the first tube, and have the support structure wound helically around the membrane, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,* 86 USPQ 70. Furthermore, the feature of having the spaced apart distance being less than or equal to 1.5 times the outer diameter of the needle is a matter of obvious design choice within the realm of one with ordinary skill in the art as it would be necessary to inhibit tearing of membrane.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

De Goicoechea et al.	U.S. Patent No. 5,383,927
Popadiuk et al.	U.S. Patent No. 5,556,426
Mano et al.	U.S. Patent No. 4,306,318
Pinchuk	U.S. Patent No. 4,629,458

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn Mathew whose telephone number is (703) 305-2846. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

fcm
August 8, 2002

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700